capturing the needle carried by the forward-deploying needle carrier in the needle catch.

20. (Amended) A method for shortening the pelvic floor comprising the steps of:

placing a suturing instrument enclosing a forward-deploying needle carrier including a needle adjacent to tissue of the pelvic floor;

deploying the suturing instrument such that a suture attached to the needle is passed through the tissue of the pelvic floor;

retrieving the suture through the tissue of the pelvic floor; and

tightening the suture such that the pelvic floor buckles and is effectively shortened in height.

REMARKS

Status of the Claims

Claims 1-23 are pending in this application. Claims 1, 7-9, 11-13, and 20 are amended. Claims 1, 11, 13, and 20 are the independent claims now pending. In light of the amendments and remarks presented herein, reconsideration and allowance of the claims are respectfully requested.

Objections to the Specification

The Office action objects to the Abstract for failure to fully describe the invention. Applicants hereby amend the Abstract to better describe the invention and to increase the number of words to exceed 50. No new matter has been introduced by this amendment. Support for the amended Abstract can be found in, for example, the specification on page 1, lines 21-27. Applicants respectfully submit that after entry of the present Amendment, the Abstract is sufficiently descriptive of the invention.

The Office action also objects to the Specification because of a number of informalities. The specification is hereby amended to correct all the informalities noted in the Office action and

to address certain inconsistencies in terminology used in the Specification. No new matter has been added.

The Specification is further objected to as failing to provide proper antecedent basis for the term "needle carrier channel" recited in claim 17. Applicants respectfully point out that the required support can be found in the Specification at least on page 3, lines 3-6 and page 4, lines 4-5 and 18-26.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the objections to the Specification.

Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 11 and 12 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. Applicants hereby rewrite claim 11 in independent form to describe more clearly the location of the distal tip assembly and amend claim 12 to depend from claim 11, instead of claim 1. Claim 11 now recites, in part, a distal tip assembly coupled to the elongate body member and a needle catch and forward-directed exit port disposed on a front face of the distal tip assembly. Support for this amendment can be found, for example, on page 3, lines 19-25 and in FIGS. 8A-8D.

In view of the foregoing, Applicants respectfully request that the rejections under 35 U.S.C. § 112, second paragraph, be reconsidered and withdrawn.

Claim Objections

Claim 7 is objected to because of an extra period at the end of the sentence. Applicants hereby amend claim 7 to correct the informality. Claim 9 has been amended to correct a similar informality.

Rejections under 35 U.S.C. § 102(b)

A. Gordon I Does Not Anticipate the Claimed Invention

Claims 1-9 and 13-19 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,458,609 to Gordon *et al.* ("Gordon I"). Without acquiescing in the rejection, Applicants hereby amend claim 1 to recite, in part, a forward-directed exit port and a needle catch that are disposed on a front face of the distal portion of the elongate body member. Applicants further amend claim 13 to recite, in part, a method for placing a suture in tissue comprising a step of positioning the target tissue between a forward-directed exit port and a needle catch that are disposed on a front face of a distal end of the suturing instrument. Support for the amendments made to claims 1 and 13 can be found, for example, on page 6, lines 23-29 and in FIGS. 2 and 9A-9D. In light of these amendments, Applicants respectfully submit that Gordon I does not teach or suggest every limitation of amended independent claims 1 and 13, or claims 2-9 and 14-19, which depend either directly or indirectly therefrom.

Specifically, Gordon I does not teach the recited forward-directed exit port and needle catch of amended claim 1 and the recited step of positioning the target tissue between the exit port and the needle catch of amended claim 13. Instead, Gordon I teaches a needle carrier 84a that is deployed from the side of a housing 32 and a needle catch 78a that is disposed on the side of the housing 32, as shown in, for example, FIGS. 11-15 of Gordon I. Accordingly, Gordon I does not teach or suggest either the forward-directed exit port and needle catch disposed on a front face of the distal portion of the elongate member or the step of positioning tissue to be sutured between the forward-directed exit port and the needle catch disposed on a front face of a distal end of the suturing instrument, as recited in amended claims 1 and 13, respectively. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of

claims 1 and 13 based on Gordon I. Because claims 2-8 and 14-19 depend directly or indirectly from amended independent claims 1 and 13, respectively, these claims are patentable as well.

B. Gordon II Does Not Anticipate the Claimed Invention

Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,048,351 to Gordon *et al.* ("Gordon II"). Applicants respectfully traverse this rejection, and submit that Gordon II does not teach every limitation of amended independent claim 11. Specifically, Gordon II does not teach a distal tip assembly that comprises a needle catch and an exit port disposed on a front face of the distal tip assembly, as recited in amended claim 11. Instead, Gordon II's needle catch 360 and exit port are disposed on a side surface of distal tip 306 of the instrument 300. See FIGS. 16, 17A-17D, and column 22, lines 9-14, of Gordon II. Accordingly, Applicants request reconsideration and withdrawal of the rejection of claim 11 based on Gordon II.

C. Daniel Fails to Anticipate the Claimed Invention

Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,860,992 to Daniel *et al.* ("Daniel"). Applicants respectfully traverse this rejection, and submit that Daniel fails to teach every limitation of amended claim 12. Specifically, Daniel fails to teach or suggest a distal tip assembly that is capable of being rotated axially about a longitudinal axis with respect to the elongate body member, as recited in amended independent claim 11, from which claim 12 directly depends. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 12 based on Daniel.

D. Claren Fails to Anticipate the Claimed Invention

Claims 20-23 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,899,909 to Claren *et al.* ("Claren"). Without acquiescing in the rejection, Applicants hereby amend claim 20 to recite a method for shortening the pelvic floor comprising the steps of placing

a suturing instrument enclosing a forward-deploying needle carrier including a needle adjacent to tissue of the pelvic floor; deploying the suturing instrument such that a suture attached to the needle is passed through the tissue of the pelvic floor; retrieving the suture through the tissue of the pelvic floor; and tightening the suture such that the pelvic floor buckles and is effectively shortened in height. Support for this amendment can be found, for example, on page 10, lines 19-29; page 11, lines 1-20; and in FIGS. 9A-9D and 10A-10F. In light of the amendment, Applicants respectfully submit that Claren fails to teach every limitation of amended independent claim 20.

Specifically, Claren's method for implanting tape 26 comprises penetration of the vaginal wall by a first needle 21A being passed close to the back of the pubic bone 31 and then through the abdominal wall above the pubic bone. The needle 21A is withdrawn from the abdominal wall by means of forceps. The other needle 21B is passed through the incision in the vaginal wall, through the abdominal wall, and then is withdrawn from the abdominal wall. See column 3, line 48, to column 4, line 15, of Claren.

In distinct contrast, Applicants' claimed method is significantly less intrusive that that disclosed in Claren. In Applicants' method, the instrument is positioned adjacent the pelvic floor and a needle and suture are deployed and retrieved through the pelvic floor only. See Applicants' FIGS. 10A-10F.

Since Claren fails to teach or suggest at least the step of retrieving the suture through the tissue of the pelvic floor as recited in amended independent claim 20, Applicants respectfully submit that claim 20 is patentable over Claren. Specifically, Claren discloses retrieving the needles 21A, 21B through the abdominal wall, not the pelvic floor. Because claims 21-23 depend either directly or indirectly from amended independent claim 20, these claims are

patentable as well. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 20-23 based on Claren.

Rejection under 35 U.S.C. § 103(a)

Claim 10 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Gordon I. Without reaching the merits of or acquiescing to the rejection with respect to claim 10, Applicants respectfully submit that because amended independent claim 1 is patentable over Gordon I, as described above, claim 10 also is patentable as well, because it depends directly from claim 1. In light of the foregoing, Applicants respectfully request that this rejection be reconsidered and withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration, withdrawal of all grounds of objection and rejection, and allowance of claims 1-23 in due course. The Examiner is invited to contact Applicants' undersigned representative by telephone at the number listed below to discuss any outstanding issues.

Respectfully submitted,

Date: May 12, 2003
Reg. No. 42,545

John V. Forcier
Attorney for the Applicants
Testa, Hurwitz, & Thibeault, LLP
125 High Street
Boston, Massachusetts 02110

Tel. No.: (617) 248-7675
Fax No.: (617) 248-7100

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MARKED-UP VERSION OF AMENDMENTS

In the Abstract:

The present invention allows for the performance of surgical procedures that involve the passing of sutures through tissue in a location that is facilitated by the suturing instrument deploying the suture in a forward-facing direction in relation to the suturing instrument. In addition, this invention provides for the catching and retrieval of the suture after it is passed through the tissue. In particular, this suturing instrument may be placed or positioned in the body such that a suture may be passed into a tissue of the body while the face of the distal end of the instrument abuts the tissue. ~~**Sutures can be placed in difficult to access areas of the human body with devices, and related methods, utilizing a needle carrier. The devices and methods can be used in conjunction with both endosurgical and traditional open surgery procedures**~~.

In the Specification:

- Page two, first, second, and third full paragraphs.

In one aspect, the invention relates to a suturing instrument. The suturing instrument includes an elongate body member, a needle deployment system disposed at a distal portion of the elongate body member. The **needle** ~~**suture**~~ deployment system includes a forward-deploying needle carrier including a needle for tissue penetration and a catch to receive and retain the needle. The inclusion of a needle catch in the needle deployment system prevents the need for the introduction of a second surgical instrument into the location of the body where the suture was passed in order to retrieve the suture.

In some embodiments, the suturing instrument may include a deployment controller having a proximal end and a distal end. The deployment controller extends substantially along a longitudinal axis of the elongate body member to the distal portion of the elongate body member, where the distal end of the deployment controller is coupled to the needle carrier and moves the **needle** ~~**suture**~~ carrier between a retracted position and a deployed position. The proximal end of the deployment controller may be coupled to an actuator. In some embodiments, the deployment controller guides the **needle** ~~**suture**~~ carrier along a path which includes a proximal curved path

segment such that the needle carrier initially travels away from the elongate body member and then toward the elongate body member.

Various embodiments according to the foregoing aspect of the invention can include the following features. A suture can include a needle, and the needle can be permanently fixed to an end of the suture. The needle fixed on the suture can insert into the needle carrier. Also, the needle can be plastic, metal, or polymer compound. In addition, the suturing instrument can include a catch to receive and retain the needle, where the catch is positioned on the **elongate** body member such that a distal segment of the needle carrier's path is intercepted by the catch. Additionally, the suturing instrument may include a second needle carrier and a second forward-**directed** ~~**facing**~~ exit port. Further, the deployment controller may be coupled to the **needle** ~~**suture**~~ carrier with a flexible driver member. The flexible driver member may be manufactured of an alloy that includes at least or exclusively nickel and titanium.

- Page two, last paragraph.

In yet another embodiment, the invention relates to a suturing instrument including an elongate body member having a longitudinal axis and a distal tip needle deployment assembly joined with a distal end of the elongate body member such that the distal tip assembly is free to rotate axially about the longitudinal axis of the elongate body member. The distal tip **needle** ~~**suture**~~ deployment assembly includes a forward-~~**facing**~~ **directed** needle exit port and a curved needle carrier channel formed in the distal tip needle deployment assembly, a curved needle carrier movably positioned in the curved needle carrier channel, a suture with an attached needle tip, and a deployment controller including a proximal end and a distal end. The deployment controller extends substantially along the longitudinal axis of the elongate body member to the distal end of the elongate body member, where the distal end of the deployment controller is coupled to the distal tip suture deployment assembly and moves the curved suture carrier through the curved suture carrier channel as the deployment controller moves between a retracted position and a deployed position. Additionally, the proximal end of the deployment controller may be coupled to an actuator.

- Page three, first full paragraph.

In still another embodiment, the invention relates to a suturing instrument including a body member defining a forward-~~facing~~ **directed** exit port and a **needle** carrier channel, a **needle** carrier movably positioned in the **needle** carrier channel, and a surgical needle attached with an interference fit on a distal end of the needle carrier. The needle carrier has a retracted position within an interior region of the body member and a deployed position exterior to the body member. The needle carrier is configured within the needle carrier channel such that the needle carrier exits the interior region of the body member through the forward-~~facing~~ **directed** exit port. In addition, the forward-~~facing~~ **directed** exit port, needle carrier channel, and needle carrier can be located in a distal tip assembly coupled to the body member, and the distal tip assembly can be coupled to the body member such that the distal tip assembly is free to rotate axially about a longitudinal axis of the body member. In addition, the needle carrier and needle catch can be located in a distal tip assembly coupled to the elongate body member at a pivot joint such that the distal tip assembly is free to deflect about the pivot joint. Such embodiments described above allow for enhanced control of the precise placement or position of the distal tip of the suturing instrument.

- Page three, last paragraph.

An additional aspect of the invention relates to a method for placing a suture in tissue. The method includes the steps of placing a suturing instrument enclosing a needle carrier having an attached needle for tissue penetration, deploying the needle carrier out of the suturing instrument through a forward-~~facing~~ **directed** exit port such that the needle carrier exits an interior region of the suturing instrument through the exit port along a path which approaches being substantially tangential to an outer surface of the suturing instrument surrounding the forward-~~facing~~ **directed** exit port, and capturing a needle attached to a suture and carried by the needle carrier in a catch that receives and retains the needle. The needle carrier is movably positioned within a needle carrier channel adjacent the tissue to be sutured.

- Page six, fourth, fifth, and sixth full paragraphs.

FIGS. 5A and 5B are perspective views of an alternate catch mechanism with a **needle** ~~suture~~ carrier.

FIG. 6 is an end view illustrating the formed **needle** ~~**suture**~~ tip catch.

FIG. 7 is a cross-sectional view of the **needle** ~~**suture**~~ tip catch shown in FIG. 6.

- Page six, eleventh full paragraph.

FIG. 1 illustrates the general structure of one embodiment of the present invention. FIG. 1 depicts a suturing instrument 100 including handle 105, an elongate body 110, a distal tip 115, and an actuator button 120. This embodiment of the present invention is particularly well suited to, for example, the fixation of sutures to the pelvic floor during a procedure to effectively shorten the pelvic floor for the treatment of hypermobility. As will become apparent, this embodiment includes features that prevent the need for positioning the target tissue between the needle exit port and the needle catch on the side of a distal tip while placing the suturing instrument in the body. The embodiment of FIG. 1 allows for the positioning of the target tissue between the needle exit port and the needle catch on the front face of the distal tip **115** during the placement of the suturing device into the body. The end of the distal tip **115** **4** may be pressed against the target tissue in order to throw a suture into the tissue.

- Page seven, second full paragraph.

The needle carrier **255** ~~**17**~~ shown in FIG. 2 is circular; however, it is contemplated that the above embodiment may be modified to include needle carriers having non-circular contours (e.g., helical, elliptical, or straight). Although a single needle carrier 255 is shown in the figure, the above configuration may in fact contain more than one needle carrier. For example, multiple needle carriers may be actuated and driven independently by dividing the deployment controls and the needle carrier drivers into separate adjacent members with separate handles or controlled by a single handle.

- Page seven, fourth full paragraph.

A needle tip 305 comprises a body 310 having a shoulder 315. The shoulder 315 is the rear surface of the needle tip body 310 that engages a catch 260 in the manner of a flange. A length of suture material 300 is inserted into a hole **320** ~~**23**~~ located on the body 310 and attached to the needle tip 305 thereby. The suturing material 300 is attached to the body 310 by any suitable means, such as crimping or adhesive bonding. It should be understood that the

illustrated arrow-shaped body 310 is merely illustrative, and the shape may be varied to fit a particular application. The needle tip 305 can be manufactured from a plastic, metal, or polymer compound and can be formed by, for example, extrusion, molding, or machining. Furthermore, the nature of the suture 300 is immaterial to the present invention. The needle tip 305 of the present invention may be used with a suture of any type, length, diameter, and characteristics.

- Page nine, last paragraph.

Moreover, distal tip 815 may be rotatable about the axis of the elongate body housing 810 as shown in FIGS. 8B-8D. For example, an actuator button 820 may be secured to the distal tip 815 through housing **810** ~~815~~. Rotation of the actuator button 820 causes a corresponding rotation of the distal tip 815. The actuator button 820 may include a directional indicator 855 such as a pointed shape on the actuator button 820 that is aligned with the plane in which the needle tip (not shown) travels during deployment of the device 800. FIGS. 8C and D depict the rotation of the distal tip 815 by 90 degrees in alternative directions from the starting position depicted in FIG. 8B. Additionally, the range of rotation of the distal tip 815 may include a complete 360 degrees about the axis of the elongate body housing 810.

- Page eleven, first full paragraph.

FIGS. 10A-F depict a surgical method for treating hypermobility in women involving the passing of two sutures into the pelvic floor. The surgical method includes placing the distal tip 1000 of a surgical device 1005 (partially shown) against the surface of the pelvic floor 1010 and deploying the device so that the needle carrier 1015, which is carrying a needle tip 1020 with an attached suture 1025, moves in the direction of the arrow and pierces the pelvic floor 1010 (FIG. 10A). The needle carrier 1015 carries a needle tip **1020** ~~1025~~ into the needle catch 1030 in the distal tip 1000. In FIG. 10B the needle carrier 1015 is retracted into the distal tip 1000, and while the needle tip is retained in the needle catch 1030 the distal tip 1000 is retracted from the surface of the pelvic floor 1010. The needle tip 1020 is extracted from the needle catch 1030 (FIG. 10B) and reloaded into the needle carrier 1015 (FIG. 10C). In FIG. 10D the suture 1025 is placed in the pelvic floor 1010 in a second location a certain distance from the first suture placement. In FIG. 10E the needle carrier 1015 is retracted into the distal tip 1000, and the needle tip is retained in the needle catch 1030. The retention of the needle tip 1020 in the needle

catch 1030 allows for the retention and control of the leading end of the suture 1025 while the distal tip 1000 is retracted from the surface of the pelvic floor 1010 (FIG. 10E). In FIG. 10F the suture 1025 remaining in the pelvic floor 1010 is tightened and tied thus causing the buckling and effective shortening of the pelvic floor 1010. The distance between the two suture placements is directly proportional to the degree to which the pelvic floor 1010 can be shortened. The degree to which the pelvic floor 1010 is shortened can also be controlled by how tightly the suture 1025 is drawn in and tied.

In the claims:

1. (Amended) A suturing instrument comprising:

an elongate body member; **and**

a needle deployment system disposed at a distal portion of the elongate body member, the needle deployment system comprising

a forward-deploying needle carrier**[; and]**

a **needle** catch **[disposed on the elongate body member]** to receive and retain **a[the]** needle**[.], and**

a forward-directed exit port, wherein the needle catch and the exit port are disposed on a front face of the distal portion of the elongate body member.

7. (Amended) A suturing instrument as defined in claim 6, wherein the needle inserts into the needle carrier.**[.]**

8. (Amended) A suturing instrument as defined in claim 1, wherein the **needle** catch is positioned **[on the elongate body member]** such that a distal path segment of the needle carrier's path is intercepted by the **needle** catch.

9. (Amended) A suturing instrument as defined in claim 2, further comprising a flexible drive member coupling the deployment controller to the needle carrier.

11. (Amended) A suturing instrument **[as defined in claim 1,] comprising:**

an elongate body member; and

[wherein the needle carrier and needle catch are located in] a distal tip assembly coupled to the elongate body member such that the distal tip assembly is **[free to rotate] capable**

of being rotated axially about a longitudinal axis with respect to the elongate body member**[.], the distal tip assembly comprising:**

a forward-deploying needle carrier,

a needle catch to receive and retain a needle, and

a forward-directed exit port, wherein the needle catch and the exit port are disposed on a front face of the distal tip assembly.

12. (Amended) A suturing instrument as defined in claim **[1]11,** wherein the **[needle carrier and needle catch are located in a]** distal tip assembly **is** coupled to the elongate body member at a pivot joint such that the distal tip assembly is free to deflect about the pivot joint.

13. (Amended) A method for placing a suture in tissue comprising the steps of:

placing a suturing instrument enclosing a forward-deploying needle carrier including a needle, wherein the forward-deploying needle carrier is movably positioned within a needle carrier channel adjacent **[the]** tissue to be sutured;

positioning the tissue between a forward-directed exit port, and a needle catch that receives and retains the needle, the exit port and the needle catch being disposed on a front face of a distal end of the suturing instrument;

deploying the forward-deploying needle carrier out of the suturing instrument through **[a] the** forward-directed exit port; and

capturing the needle carried by the forward-deploying needle carrier in **[a] the needle** catch.

20. (Amended) A method for shortening the pelvic floor comprising the steps of:

placing a suturing instrument enclosing a forward-deploying needle carrier including a needle adjacent to **[the]** tissue of the pelvic floor;

deploying the suturing instrument such that **a[the]** suture **attached to the needle** is passed through the tissue of the pelvic floor; **[and]**

retrieving the suture through the tissue of the pelvic floor; and

tightening the suture such that the pelvic floor buckles and is effectively shortened in height.